K050162

MAR 3 - 2005

Medtronic
XOMED

Summary of 510(k) Submission: CONTACT™ EMG Rotatable Endotracheal Tube

Name and address of submitter

Medtronic Xomed Inc.
6743 Southpoint Drive North
Jacksonville, Florida 32216
Contact: David S. Dodd
Phone: (904) 332-8746
Date Prepared: January 24, 2005

Identification of Devices

- Trade name: CONTACT™ EMG Rotatable Endotracheal Tube (name not finalized and may change at a later date)
- Common or usual name: Endotracheal Tube with EMG Detection electrodes, EMG ET Tube
- Classification Name(s):
  Surgical Nerve Stimulator/locator (per 21 CFR §874.1820)
  Tracheal Tube, Inflatable Cuff (per 21 CFR §868.5730 and 868.5750)
- FDA Classification: Class II

Predicate Device(s)

- Xomed EMG Endotracheal Tubes (K925640)., and
- RLN Systems Inc., Laryngeal Surface Electrode-Endotracheal Tube (LSE-ET) (K003745)

Description of Device

The CONTACT™ EMG Rotatable Endotracheal Tube is a flexible, cuffed, Endotracheal tube manufactured from silicone elastomer, reinforced with an embedded stainless steel spiral. Four stainless steel wires are longitudinally embedded in the tube and serve, over an exposed length, as a pair of sensing/recording electrodes designed to interface with an electromyographic monitor.

Continued on next page

K050162

Summary of 510(k) Submission:
CONTACT™ EMG Rotatable Endotracheal Tube, Continued

Intended Use

The CONTACT™ EMG Rotatable Endotracheal Tube is intended for use as a means of providing both an open airway for patient ventilation and for intraoperative monitoring of EMG activity of the intrinsic laryngeal musculature when connected to an appropriate EMG monitor.

The EMG Tube is indicated for use where continuous monitoring of the integrity of the nerves supplying the laryngeal musculature is required during surgical procedures.

Conclusions drawn from studies

Validity of Scientific Data	In-house laboratories conducted studies verifying the design of this device; all followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7.
Substantial Equivalence	The data presented in this Premarket Notification support that the subject device is safe and effective and performs in the same manner as the predicate devices when used in accordance with the labeled directions for use and for the specified indication(s).
Risk and Benefits	The risks of the subject device, as well as the benefits to the patient, are the same as those attributed to the use of the predicate devices.

K050162

COMPARISON OF SUBJECT DEVICE TO PREDICATE DEVICES

	Predicate Device: (K003745) RLN Systems Inc. Laryngeal Surface Electrode-ET (LSE-ET)	**Predicate Device: (K925640)** Xomed EMG Endotracheal Tube	**Subject Device:** New Xomed EMG Endotracheal Tube
Laryngeal Surface Electrode	Yes	Yes	Yes
Endolaryngeal location	Yes	Yes	Yes
Functions with commercial EMG units?	Yes	Yes	Yes
Number of discrete electrodes?	2	4	4
Number of channels?	1	2	1
Electrode Surface	Carbon w/Ag	Stainless Steel Wire	Stainless Steel Wire
Intended Use	Intended to be used as a disposable, self-adhesive electrode attached to an endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures. It is intended for use only by a licensed physician and in conjunction with a commercially available, medical grade electromyographic monitor.	Intended for use as a tracheal tube for the administration of anesthesia gases and to maintain an open airway for the patient during surgery. The EMG electrodes are intended to serve as contact electrodes with the vocal cords of the patient and when connected to an EMG monitor, the wire electrodes facilitate the intra-operative monitoring of the vocal cords for locating and mapping the Recurrent Laryngeal Nerve and its branches during surgery of the neck.	Intended for use as a means of providing both an open airway for patient ventilation and for intra-operative monitoring of EMG activity of the intrinsic laryngeal musculature when connected to an appropriate EMG monitor. The EMG Tube is indicated for use where continuous monitoring of the integrity of the nerves supplying the laryngeal musculature is required during surgical procedures.
Tube Lengths	N/A	Approx. 12.8 inches	Approx. 12.8 inches
Tube Inside Diameter	N/A	4.0 – 8.0 mm	5.0 – 8.0 mm
Tube material	N/A	Silicone	Silicone
Cuff material	N/A	Silicone	Silicone
Reinforcing material	N/A	N/A	Stainless steel wire

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 - 2005

Medtronic Xomed
c/o David Dodd
Manager, Regulatory Affairs
6743 Southpointe Drive N.
Jacksonville, Florida 32216-0980

Re: K050162
Trade/Device Name: CONTACT™ EMG Rotatable Endotracheal Tube
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: January 25, 2005
Received: January 25, 2005

Dear Mr. Dodd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050162

Device Name: CONTACT™ EMG Rotatable Endotracheal Tube

Intended Use/Indications For Use

The CONTACT™ EMG Rotatable Endotracheal Tube is intended for use as a means of providing both an open airway for patient ventilation and for intraoperative monitoring of EMG activity of the intrinsic laryngeal musculature when connected to an appropriate EMG monitor.

The EMG Tube is indicated for use where continuous monitoring of the integrity of the nerves supplying the laryngeal musculature is required during surgical procedures.

Prescription Use ✓ (Part 21 CFR Subpart D) AND/OR Over-the-Counter Use _____ (Part 21 CFR Subpart C)

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K050162